

## Drug Enforcement Administration, Justice

## § 1301.17

do so, to sign applications for the applicant by filing with the Registration Unit of the Administration a power of attorney for each such individual. The power of attorney shall be signed by a person who is authorized to sign applications under this paragraph and shall contain the signature of the individual being authorized to sign applications. The power of attorney shall be valid until revoked by the applicant.

[62 FR 13946, Mar. 24, 1997, as amended at 68 FR 37409, June 24, 2003; 68 FR 41228, July 11, 2003; 68 FR 58598, Oct. 10, 2003]

### **§ 1301.14 Filing of application; acceptance for filing; defective applications.**

(a) All applications for registration shall be submitted for filing to the Registration Unit, Drug Enforcement Administration, Department of Justice, Post Office Box 28083, Central Station, Washington, DC 20005. The appropriate registration fee and any required attachments must accompany the application.

(b) Any person required to obtain more than one registration may submit all applications in one package. Each application must be complete and should not refer to any accompanying application for required information.

(c) Applications submitted for filing are dated upon receipt. If found to be complete, the application will be accepted for filing. Applications failing to comply with the requirements of this part will not generally be accepted for filing. In the case of minor defects as to completeness, the Administrator may accept the application for filing with a request to the applicant for additional information. A defective application will be returned to the applicant within 10 days following its receipt with a statement of the reason for not accepting the application for filing. A defective application may be corrected and resubmitted for filing at any time; the Administrator shall accept for filing any application upon resubmission by the applicant, whether complete or not.

(d) Accepting an application for filing does not preclude any subsequent request for additional information pursuant to § 1301.15 and has no bearing on

whether the application will be granted.

[62 FR 13948, Mar. 24, 1997]

### **§ 1301.15 Additional information.**

The Administrator may require an applicant to submit such documents or written statements of fact relevant to the application as he/she deems necessary to determine whether the application should be granted. The failure of the applicant to provide such documents or statements within a reasonable time after being requested to do so shall be deemed to be a waiver by the applicant of an opportunity to present such documents or facts for consideration by the Administrator in granting or denying the application.

[62 FR 13948, Mar. 24, 1997]

### **§ 1301.16 Amendments to and withdrawal of applications.**

(a) An application may be amended or withdrawn without permission of the Administrator at any time before the date on which the applicant receives an order to show cause pursuant to § 1301.37. An application may be amended or withdrawn with permission of the Administrator at any time where good cause is shown by the applicant or where the amendment or withdrawal is in the public interest.

(b) After an application has been accepted for filing, the request by the applicant that it be returned or the failure of the applicant to respond to official correspondence regarding the application, when sent by registered or certified mail, return receipt requested, shall be deemed to be a withdrawal of the application.

[62 FR 13949, Mar. 24, 1997]

### **§ 1301.17 Special procedures for certain applications.**

(a) If, at the time of application for registration of a new pharmacy, the pharmacy has been issued a license from the appropriate State licensing agency, the applicant may include with his/her application an affidavit as to the existence of the State license in the following form:

§ 1301.17

21 CFR Ch. II (4-1-05 Edition)

Affidavit for New Pharmacy

I, \_\_\_\_\_, the  
 \_\_\_\_\_ (Title of officer, official,  
 partner, or other position) of  
 \_\_\_\_\_ (Corporation, partner-  
 ship, or sole proprietor), doing business as  
 \_\_\_\_\_ (Store name) at  
 \_\_\_\_\_ (Number and Street),  
 \_\_\_\_\_ (City) \_\_\_\_\_ (State)  
 \_\_\_\_\_ (Zip code), hereby certify that  
 said store was issued a pharmacy permit No.  
 \_\_\_\_\_ by the \_\_\_\_\_ (Board of  
 Pharmacy or Licensing Agency) of the State of  
 \_\_\_\_\_ on \_\_\_\_\_ (Date).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number. I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally and the above-named corporation/partnership/business to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than \$30,000 or both.

Signature (Person who signs Application for Registration)  
 State of \_\_\_\_\_  
 County of \_\_\_\_\_

Subscribed to and sworn before me this  
 day of \_\_\_\_\_, 19\_\_\_\_.

Notary Public

(b) Whenever the ownership of a pharmacy is being transferred from one person to another, if the transferee owns at least one other pharmacy licensed in the same State as the one the ownership of which is being transferred, the transferee may apply for registration prior to the date of transfer. The Administrator may register the applicant and authorize him to obtain controlled substances at the time of transfer. Such registration shall not authorize the transferee to dispense controlled substances until the pharmacy has been issued a valid State license. The transferee shall include with his/her application the following affidavit:

Affidavit for Transfer of Pharmacy

I, \_\_\_\_\_, the  
 \_\_\_\_\_ (Title of officer, official,  
 partner or other position) of  
 \_\_\_\_\_ (Corporation, partner-  
 ship, or sole proprietor), doing business as

\_\_\_\_\_ (Store name) hereby certify:

(1) That said company was issued a pharmacy permit No. \_\_\_\_\_ by the  
 \_\_\_\_\_ (Board of Pharmacy of  
 Licensing Agency) of the State of  
 \_\_\_\_\_ and a DEA Registration Number  
 \_\_\_\_\_ for a pharmacy located at  
 \_\_\_\_\_ (Number and Street)  
 \_\_\_\_\_ (City) \_\_\_\_\_ (State)  
 \_\_\_\_\_ (Zip Code); and

(2) That said company is acquiring the pharmacy business of \_\_\_\_\_ (Name  
 of Seller) doing business  
 as \_\_\_\_\_ with DEA Registration  
 Number \_\_\_\_\_ on or about \_\_\_\_\_  
 (Date of Transfer) and that said company has  
 applied (or will apply on \_\_\_\_\_ (Date)  
 for a pharmacy permit from the board of  
 pharmacy (or licensing agency) of the State  
 of \_\_\_\_\_ to do business as  
 \_\_\_\_\_ (Store name) at  
 \_\_\_\_\_ (Number and Street)  
 \_\_\_\_\_ (City) \_\_\_\_\_ (State)  
 \_\_\_\_\_ (Zip Code).

This statement is submitted in order to obtain a Drug Enforcement Administration registration number.

I understand that if a DEA registration number is issued, the pharmacy may acquire controlled substances but may not dispense them until a pharmacy permit or license is issued by the State board of pharmacy or licensing agency.

I understand that if any information is false, the Administration may immediately suspend the registration for this store and commence proceedings to revoke under 21 U.S.C. 824(a) because of the danger to public health and safety. I further understand that any false information contained in this affidavit may subject me personally to prosecution under 21 U.S.C. 843, the penalties for conviction of which include imprisonment for up to 4 years, a fine of not more than \$30,000 or both.

Signature (Person who signs Application for Registration)  
 State of \_\_\_\_\_  
 County of \_\_\_\_\_

Subscribed to and sworn before me  
 this day of \_\_\_\_\_, 19\_\_\_\_.

Notary Public

(c) The Administrator shall follow the normal procedures for approving an application to verify the statements in the affidavit. If the statements prove to be false, the Administrator may revoke the registration on the basis of section 304(a)(1) of the Act (21 U.S.C. 824(a)(1)) and suspend the registration

## Drug Enforcement Administration, Justice

## § 1301.18

immediately by pending revocation on the basis of section 304(d) of the Act (21 U.S.C. 824(d)). At the same time, the Administrator may seize and place under seal all controlled substances possessed by the applicant under section 304(f) of the Act (21 U.S.C. 824(f)). Intentional misuse of the affidavit procedure may subject the applicant to prosecution for fraud under section 403(a)(4) of the Act (21 U.S.C. 843(a)(4)), and obtaining controlled substances through registration by fraudulent means may subject the applicant to prosecution under section 403(a)(3) of the Act (21 U.S.C. 843(a)(3)). The penalties for conviction of either offense include imprisonment for up to 4 years, a fine not exceeding \$30,000 or both.

[62 FR 13949, Mar. 24, 1997]

### § 1301.18 Research protocols.

(a) A protocol to conduct research with controlled substances listed in Schedule I shall be in the following form and contain the following information where applicable:

(1) Investigator:

(i) Name, address, and DEA registration number; if any.

(ii) Institutional affiliation.

(iii) Qualifications, including a curriculum vitae and an appropriate bibliography (list of publications).

(2) Research project:

(i) Title of project.

(ii) Statement of the purpose.

(iii) Name of the controlled substances or substances involved and the amount of each needed.

(iv) Description of the research to be conducted, including the number and species of research subjects, the dosage to be administered, the route and method of administration, and the duration of the project.

(v) Location where the research will be conducted.

(vi) Statement of the security provisions for storing the controlled substances (in accordance with §1301.75) and for dispensing the controlled substances in order to prevent diversion.

(vii) If the investigator desires to manufacture or import any controlled substance listed in paragraph (a)(2)(iii) of this section, a statement of the quantity to be manufactured or imported and the sources of the chemicals

to be used or the substance to be imported.

(3) Authority:

(i) Institutional approval.

(ii) Approval of a Human Research Committee for human studies.

(iii) Indication of an approved active Notice of Claimed Investigational Exemption for a New Drug (number).

(iv) Indication of an approved funded grant (number), if any.

(b) In the case of a clinical investigation with controlled substances listed in Schedule I, the applicant shall submit three copies of a Notice of Claimed Investigational Exemption for a New Drug (IND) together with a statement of the security provisions (as prescribed in paragraph (a)(2)(vi) of this section for a research protocol) to, and have such submission approved by, the Food and Drug Administration as required in 21 U.S.C. 355(i) and §130.3 of this title. Submission of this Notice and statement to the Food and Drug Administration shall be in lieu of a research protocol to the Administration as required in paragraph (a) of this section. The applicant, when applying for registration with the Administration, shall indicate that such notice has been submitted to the Food and Drug Administration by submitting to the Administration with his/her DEA Form 225 three copies of the following certificate:

I hereby certify that on \_\_\_\_\_  
(Date), pursuant to 21 U.S.C. 355(i) and 21  
CFR 130.3, I, \_\_\_\_\_ (Name and  
Address of IND Sponsor) submitted a Notice  
of Claimed Investigational Exemption for a  
New Drug (IND) to the Food and Drug Ad-  
ministration for:

\_\_\_\_\_  
(Name of Investigational Drug).

\_\_\_\_\_  
(Date)

\_\_\_\_\_  
(Signature of Applicant).

(c) In the event that the registrant desires to increase the quantity of a controlled substance used for an approved research project, he/she shall submit a request to the Registration Unit, Drug Enforcement Administration, Post Office Box 28083, Central Station, Washington, DC 20005, by registered mail, return receipt requested. The request shall contain the following